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EMG Activity of Accessory Muscles of Breathing during Recovery Positions

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EMG ACTIVITY OF ACCESSORY MUSCLES OF BREATHING
DURING RECOVERY POSITIONS

by

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A Scholarly Project Submitted to the Graduate Faculty of the

Department of Physical Therapy

School of Medicine and Health Sciences

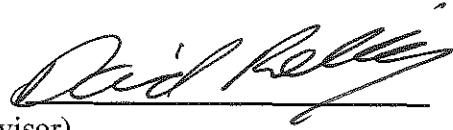
University of North Dakota

in partial fulfillment of the requirements for the degree of

Doctor of Physical Therapy

Grand Forks, North Dakota
May, 2016

This Scholarly Project, submitted by Joel Kramer, Kelsey Meyer, Eric Nefstead, and Daniel Vilaubi in partial fulfillment of the requirements for the Degree of Doctor of Physical Therapy from the University of North Dakota, has been read by the Advisor and Chairperson of Physical Therapy under whom the work has been done and is hereby approved.

A handwritten signature in cursive script, appearing to read "David Kelley", written over a horizontal line.

(Graduate School Advisor)

A handwritten signature in cursive script, appearing to read "David Kelley", written over a horizontal line.

(Chairperson, Physical Therapy)

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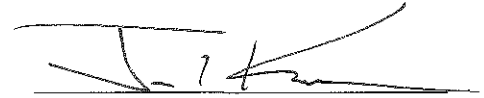
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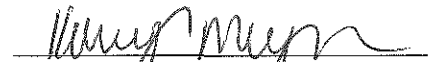
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ABSTRACT

Chronic obstructive pulmonary disease (COPD) is predicted to become the third leading cause of death worldwide between 2020 and 2030.^{1,2,3} Signs and symptoms of this disease can be debilitating, however techniques can be taught to decrease impairments. Suggested techniques for pulmonary recovery consist of supporting the upper extremities, supporting the head and leaning forward. The purpose of the current study was to examine the effects of recovery positions on the EMG activation of accessory muscles of respiration to decipher which recovery position is the most ideal for COPD patients. Fourteen healthy adults over the age of eighteen were recruited for this study. Bilateral EMG surface electrodes were placed on the accessory muscles of breathing including upper trapezius, sternocleidomastoid, pectoralis major (clavicular head), serratus anterior and latissimus dorsi. The subjects were randomly assigned a series of four different experimental positions: control position with the hands at the sides, standing with hands overhead, leaning forward with hands on knees and sitting with forearms and hands supported by a table. In each position, EMG activity was collected during three separate trials of maximal inspiration and maximal expiration. Results indicated a significantly higher level of bilateral EMG activity in the upper trapezius and serratus anterior in the hands on head position and of the latissimus dorsi during the hands on knees position. In conclusion, standing with hands on head and standing with hands on knees are two positions that are significantly advantageous for activating respiratory accessory muscles and could be utilized by COPD patients during respiratory recovery.

CHAPTER I

INTRODUCTION

Chronic obstructive pulmonary disease (COPD) is an umbrella term used to describe a multitude of chronic lung diseases that impair lung airflow.¹ Lung diseases typically identified under the term COPD are a leading cause of mortality and are predicted to become the third leading cause of death worldwide between 2020 and 2030.^{1,2,3} COPD has a prevalence estimated at 4-10% worldwide and 37% in the United States.^{4,5} Men, smokers and people greater than 40 years of age have the highest prevalence of COPD which dramatically increases above the age of 75.^{4,5} Risk factors include cigarette smoking, decreased activity and occupational exposures, such as organic and inorganic dusts, chemical agents and fumes.⁴ Some causes can be from chronic abnormal inflammatory response of lung to noxious particles or gases that result in small airway disease, such as obstructive bronchiolitis, and parenchymal destruction, such as in emphysema. Symptoms include cough, sputum production, wheezing, but most importantly dyspnea leading to decreased activity. Likely contributing factors to dyspnea include pulmonary hypertension, secondary polycythemia, systemic inflammation, and skeletal muscle dysfunction. It has also been documented that a combination of these factors leads to diminished quality of life, reduced exercise tolerance, increased risk of cardiovascular morbidity, and greater risk of death.² When dyspnea is present, overall lung function can be evaluated with spirometry.

Spirometry testing for patients with COPD continues to gain clinical interest as an important tool to assess disease severity, functional ability and lung capacities. Although

spirometry can be utilized for many pulmonary diseases, when used for dyspnea the FEV₁ was moderately correlated with patients' ratings of dyspnea ($r=0.29$; 95% CI, 0.22 to 0.35).⁶ Furthermore, spirometry has been used as an outcome measure of therapy, as well as for prognostic purposes. It has been established that spirometry lung volumes, specifically vital capacity, is reduced in most patients with COPD compared to healthy individuals.⁷ The higher the severity of the individual's COPD, the lower the spirometry values will be. Studies show that physicians underutilize spirometry for diagnosis of COPD, which leads to underestimation of disease severity and diagnosis.^{8,9} With proper training, it has been shown that knowledge of spirometry use increases and helps physicians more properly diagnose COPD.¹⁰

Electromyography (EMG) is widely used as an important tool to assess muscular activity, including the activity of respiratory accessory muscles, which are more often utilized with people suffering from COPD. The reproducibility of the EMG technique was studied among COPD patients and healthy subjects. It was concluded that this technique has acceptable reproducibility in both groups of participants. It was also sensitive enough to detect different breathing patterns when breathing against increasing inspiratory loads.¹¹ Therefore, EMG has been proven to be a good tool to detect and assess the action potentials of respiratory accessory muscular tissue.

In therapy, patients with COPD are often taught techniques to increase lung capacity, clear airways, conserve energy and recover from strenuous activities. Suggested positions for pulmonary recovery include supporting the upper extremities, supporting the head and leaning forward. Patients should be encouraged to perform the position that helps their inspiratory

muscles recover the fastest. It has been shown in patients with COPD that a forward leaning trunk position has relieved dyspnea.¹² Along with the forward leaning posture and head and neck in neutral alignment, it has been shown to reduce airway obstruction, which may increase pulmonary function.¹² Forward leaning with arm support and forward leaning with head and arm support induced increased activity of inspiratory accessory muscles during inspiration compared to neutral sitting positions for patients with COPD.¹² However, there is limited research that compares the different positions.

The forward leaning position also has been found to be associated with a significant reduction in EMG activity of the scalene and sternocleidomastoid muscles.¹³ According to research, when dyspnea and inspiratory efforts are increased, EMG activity of the scalene muscles are also increased.¹⁴ According to an article published in the *Brazilian Journal of Physical Therapy*, there is an increase in sternocleidomastoid activity with unsupported arm elevation while performing ADL's.¹⁵ During the use of unsupported arm elevation, two factors become determinants of the altered respiratory pattern: lung hyperinflation and, to a small degree, diaphragm reserve strength. Due to dynamic hyperinflation during inspiration, the respiratory muscles are placed in an unfavorable position on the length-tension curve, reducing the strength generation capacity.¹⁵ During arm elevation at rest, there was a significant decrease in vital capacity and a small decrease in functional residual capacity.⁷

In addition to varying recovery positions, there are also a variety of inspiratory muscles that assist in breathing. These skeletal muscles play an essential role in providing the mechanical basis for respiration and movement.³ The muscles utilized may include upper and middle trapezius, latissimus dorsi, pectoralis major, erector spinae, internal and external

obliques, intercostals, abdominals and serratus anterior.² Skeletal muscle dysfunction is prevalent in all stages of COPD and significantly influences symptoms, functional capacity, health-related quality of life, health resource usage and even mortality.³ Lomax et al. compared the EMG activity of accessory inspiratory muscles of eight college swimmers after front crawl sprints. It was concluded that inspiratory muscle fatigue affected the activity of latissimus dorsi during the sprints. Another study looked at the effects of a physical therapy program on accessory inspiratory muscle usage. After body posture realignment and respiratory training, the EMG recordings indicated less effort of the accessory inspiratory muscles.¹⁶ There are numerous factors that can potentially affect inspiratory muscle activity, but further research is needed to conclude which muscles assist the most and during what phase of breathing.

The aim of the current study is to investigate the effects of recovery positions on the EMG activation of accessory muscles of respiration and dynamic pulmonary function using a hand held spirometer. The data from this study may be utilized to determine which recovery positions may be the most effective for patients with COPD.

CHAPTER II

METHODS

This project was reviewed and approved by the University of North Dakota Institutional Review Board (IRB-201505-361) prior to initiation of the study (See Appendix).

Subjects

Subjects were recruited from a sample of convenience at the physical therapy department at the University of North Dakota. The subjects participating in this study were obtained on a voluntary basis and all subjects completed an informed consent form prior to participation. (See Appendix) The selection criteria included healthy adults over the age of 18. The exclusion criteria included breathing difficulty with physical activity, injuries to the chest or back in the past three months, and allergic reactions to adhesives. Each subject completed a subject questionnaire and data collection form. The subjects attended one day of testing in the Department of Physical Therapy on the University of North Dakota campus in the School of Medicine and Health Sciences. The testing was completed in a private research room for the confidentiality and privacy of the subjects. Subjects did not receive compensation for participating in this study.

Instrumentation

Instrumentation for this study included electromyography hardware and software. The electromyography (EMG) data collection was performed using self-adhesive pre-gelled EMG

surface electrodes over standard electrode sites of the following muscles: upper trapezius, sternocleidomastoid, pectoralis major (clavicular head), serratus anterior and latissimus dorsi. The EMG data was collected using the Noraxon MyoResearch XP software and the TeleMyo 2400 G2 telemetry system. Data analysis for the raw EMG data was performed on a laptop computer (Dell, Round Rock TX) using Noraxon MyoResearchXP software (Noraxon, USA, Scottsdale AZ).

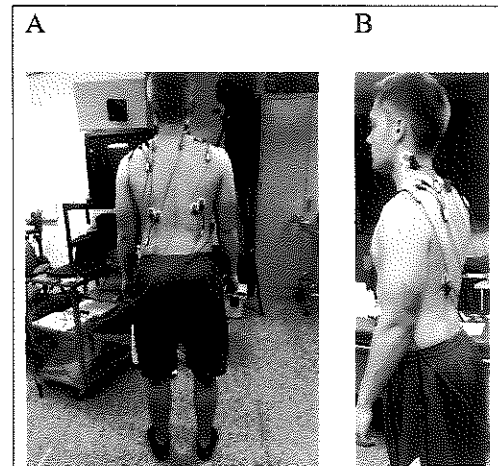


Figure 1.A&B. EMG Electrode placement for the accessory muscles of respiration used during the study.

Procedure

Prior to the initiation of the study, the EMG equipment was set up and tested by the researchers to ensure proper signal transmission and reception. The subjects were tested independently in the Department of Physical Therapy located at the University of North Dakota School of Medicine and Health Sciences. The purpose and procedure for the study were explained to the participants prior to each participant signing a statement of informed

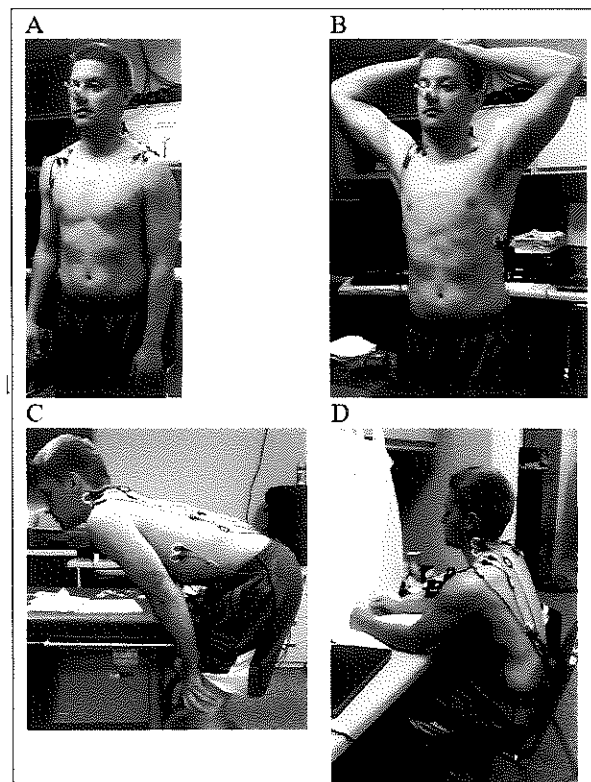


Figure 2. Pulmonary recovery positions of A. Neutral, B. Hands on head, C. Hands on knees, and D. Seated with elbows on table.

consent, completing the intake survey, and initiation of data collection.

The collection of EMG data required electrode site preparation, electrode placement, connecting and testing the equipment. The electrode site preparation was performed in a standardized fashion including removal of excess hair from the electrode site with an electric razor, swiping the skin surface with 400 grit sandpaper, and wiping the area with an isopropyl alcohol saturated towel. Electrode placement was determined by using standard electrode placement recommendations.(Criswell 2011) Standard silver/silver chloride electrodes were placed in a bipolar configuration at the appropriate sites using an inter-electrode distance of approximately 1.5 cm. Skin impedance was assessed to be under 50 kOhm using the Noraxon impedance analyzer (Noraxon, USA, Scottsdale AZ). The electrodes were connected to the Telemyo 2400 G2 transmitter. (Figure 1A&B) The EMG signals were transmitted to the Telemyo 2400 G2 receiver and stored on a laptop computer (Dell Inc.). The raw EMG data was later analyzed for intensity of activation of the muscles using the MyoResearch XP software. (Noraxon USA, Inc. Scottsdale AZ)

Each subject performed mild muscle contractions to confirm appropriate electrode placement and EMG equipment configuration. After the mild muscle contractions, the subjects were instructed in performing maximal voluntary contractions (MVC) for the upper trapezius, sternocleidomastoid, latissimus dorsi, and pectoralis major. The serratus anterior MVC was determined from the MVC position for the pectoralis major muscle.

The subjects were randomly assigned a series of four different experimental positions including the control position with the hands at the sides, standing with hands overhead, leaning forward with hands on knees and sitting with forearms and hands supported by a

table. (See Figure 2 A-D) In each position, EMG activity was collected during three separate trials of maximal inspiration and maximal expiration using a hand-held spirometer. (Jaeger SpiroPro+® SensorMedics Corp. Yorba Linda CA) The ventilatory volumes retained for further analysis included the vital capacity of inspiration (VC_{in}), forced expiratory volume in one second (FEV₁), and forced vital capacity (FVC). During spirometry, the subjects utilized a nose clip to minimize error. One of the researchers held the spirometer at a comfortable position for the subject while the subject performed a slow, deep inspiration followed by a forceful expiration and forceful inspiration. An average of three attempts in each position were used for analysis. The spirometric measurements were followed by a trial of maximal voluntary ventilation (MVV) for 10 seconds in the same position. The volume of air moved during the MVV was not collected for analysis. Following the completion of data collection in all experimental positions, the electrodes were removed from the subjects followed by cleaning the areas with an isopropyl alcohol soaked towel.

Data Analysis

Raw EMG data was analyzed using the Noraxon Myoresearch Software Program. The EMG data was normalized to the maximal voluntary contractions, rectified, and smoothed using the root mean square (RMS) over 50 ms. collection frames. Composite data is presented as average \pm SD for all subjects within an experimental condition.

Statistical Analysis

Data are presented as mean \pm standard deviation. A one-way, repeated measures analysis of variance was utilized to determine differences between the experimental trials for each

individual muscle ($\alpha=0.05$). The least significant difference post hoc test was utilized when appropriate.

CHAPTER III

RESULTS

Fourteen subjects participated in the study including six females and eight males (see Table 1). The data and analysis are combined for reporting purposes. The average age of the subjects was 24 ± 2 . The average height of the subjects was 67.4 ± 3.4 inches while the average weight was 160 ± 23 pounds.

	N	Age	Height (in)	Weight (lbs.)
Female	6	23	64.2 ± 1.8	139 ± 19
Male	8	25	69.9 ± 1.7	176 ± 11
Total	14	24	67.4 ± 3.4	160 ± 23

A one-way repeated measures ANOVA was calculated comparing bilateral EMG activity of the upper trapezius, serratus anterior, and latissimus dorsi of 14 subjects in four different positions: arms at sides, hands on head, hands on knees, and arms supported on table (Figure 2A-D). A significantly higher level of bilateral EMG activity was observed in the upper trapezius and serratus anterior in the hands on head position. A significantly elevated level of bilateral EMG activity was observed in the latissimus dorsi muscle during the hands on knees position. (See Table 2) At the same time, a one-way repeated measures ANOVA was calculated comparing EMG activity of sternocleidomastoid and pectoralis major bilaterally of the same 14 subjects in four different positions: arms at sides, hands on head, hands on knees, and arms supported on table. No significant effect was found for the EMG activity observed in the sternocleidomastoid and pectoralis major muscles. (See Table 2)

Muscle	Hands at Side (M±SD)	Hands on Head (M±SD)	Hands on Knees (M±SD)	Arms supported on table (M±SD)	F value
R Upper Trap	5.2±5.4	19.8±12.4	6.0±7.9	9.0±8.2	F(3,14)=20.678, p<0.001, η=.614, power=1.0
L Upper Trap	5.8±3.8	22.0±16.2	6.2±5.0	10.0±7.4	F(3,14)=12.773, p=.003, η=.496, power=.91
R SCM	26.0±17.2	23.6±13.4	21.1±15.9	23.4±13.3	NSD, power=.584
L SCM	23.6±13.8	21.9±11.6	23.9±16.2	24.9±12.5	NSD, power=.209
R Pec Major	6.7±5.9	6.1±4.5	13.4±12.4	8.1±6.1	NSD, power=.497
L Pec Major	7.3±5.8	12.0±8.0	13.9±10.0	13.6±16.7	NSD, power=.213
R Serratus Ant	10.1±6.3	22.7±12.0	15.0±13.4	7.7±5.4	F(3,14)=11.509, p=0.005, η=.470, power=.880
L Serratus Ant	14.3±11.6	34.7±32.6	17.4±16.3	11.8±10.8	F(3,14)=7.926, p=0.015, η=.379, power=.740
R Lat	12.9±8.5	10.5±6.6	22.3±11.6	14.9±11.6	F(3,14)=7.898, p=0.015, η=.378, power=.738
L Lat	13.4±8.7	11.2±7.5	21.6±9.9	14.7±11.6	F(3,14)=9.733, p<0.001, η=.428, power=.995

A one-way repeated measures ANOVA was calculated comparing VCin, FVC, and FEV₁ average values of 14 subjects in four different positions: arms at sides, hands on head, hands on knees, and arms supported on table. No significant effect was observed for the pulmonary ventilation values. (See Table 3).

Pulmonary Measure	Hands at Side (M±SD)	Hands on Head (M±SD)	Hands on Knees (M±SD)	Arms supported on table (M±SD)	F value
VCin	4.5±0.9	4.5±.9	4.6±1.1	4.5±1.0	NSD, power=.175
FVC	4.6±0.9	4.6±0.9	4.7±1.1	4.7±1.0	NSD, power=.141
FEV₁	4.0±0.7	4.0±0.6	4.1±0.7	4.0±0.8	NSD, power=.564

CHAPTER IV

DISCUSSION

This study aimed to find the effects of respiratory recovery positions on the EMG activity of accessory muscles of respiration and pulmonary function using a handheld spirometer. The sample subjects tested were healthy, young adults. Data was applied and related to COPD to determine which recovery positions may be the most effective for dyspnea associated with reduced pulmonary ventilation.

No significant effect was found comparing EMG activity of the sternocleidomastoid and pectoralis major in each of the four positions. Also, no significant effect was found when comparing the four different positions and their respective spirometry values. This is consistent with previous studies that also examined maximal inspiratory and expiratory pressures with a spirometer. Bhatt et al. researched spirometry, maximal inspiratory and expiratory measures, and diaphragmatic excursion during tidal and vital capacity. The specific positions tested were sitting, supine, and tripod, which consisted of sitting forward with hands supported on the knees. Although the tripod position is not identical to any of the four positions in the current study, it is similar to a combination of sitting with elbows supported and standing with hands on knees. It was found that there is no difference in the tripod position compared to sitting and supine positions measuring spirometry, maximal inspiratory and expiratory pressures and diaphragmatic excursion.¹⁷ Therefore, the results of the current

study parallel previous research in concluding that there are no pulmonary differences in recovery positions compared to a control position.

Although the different recovery positions do not provide a significant difference in lung volumes, the positions have shown changes in how respiratory muscles are utilized. The results of the current study concluded that there was a significantly higher level of bilateral EMG activity of the upper trapezius and serratus anterior while participants were in the hands on head position. There was also a significantly higher level of bilateral EMG activity in the latissimus dorsi muscle during the hands on knees position. This coincides with past studies that have looked at respiratory muscles and COPD.

O'Donnell et al. reviewed the abnormalities of pulmonary gas exchange, respiratory mechanics, and compensatory adaptations of the respiratory system that develop in response to increasing physiological impairment, such as with mild COPD. It was concluded that patients with mild COPD had an increased contractile respiratory muscle effort.¹⁸ This was discussed as being a mechanism to maintain effective alveolar ventilation to compensate for pulmonary gas exchange abnormalities. Therefore, if COPD causes an increased respiratory muscle effort, it would be essential to understand what body positions could assist with respiratory muscle contraction. Creating an advantageous position for the accessory respiratory muscles would allow for better energy conservation and more efficient breathing after an increase in activity level. The current study produced results that indicate standing with hands on head and standing with hands on knees are two positions that have significantly activated respiratory accessory muscles.¹⁸

Besides increasing accessory muscle contractile force and putting the lungs in a more favorable position, the respiratory recovery positions used by many patients with COPD may have another purpose. Gosselink et al. looked at a rehabilitation program for COPD that consisted of breathing techniques, pursed lips breathing, forward leaning, active expiration, and inspiratory muscle training. Focus was put on the forward leaning posture and its potential to relieve dyspnea. It was discovered that the forward leaning posture had less to do with accessory respiratory muscles and more to do with the abdominal musculature.¹⁹ Contracted abdominals increased pressure in the abdominal cavity, which supported the diaphragm, causing a reduction in dyspnea. The forward leaning posture also showed decreased EMG activity of the scalene and sternocleidomastoid. Therefore, the forward leaning position decreased dyspnea by providing a stronger abdominal contraction that increased the support for the diaphragm while decreasing accessory muscle recruitment.¹⁹ Gerling et al. looked at the capability of the latissimus dorsi to generate force. The article found that the latissimus dorsi has the largest cross sectional area as a muscle, but lack of sarcomere distribution parallel to the muscle provides it with only moderate force production.²⁰ Despite this, the large cross sectional area can provide accessory breathing capabilities with the arms extended and, with its attachment to the trunk, moderate expansion of the chest for breathing. In the current study, this was shown with the EMG results in the hands on knees position, as the latissimus dorsi had increased EMG activity while the upper extremities were extended in weight bearing, which allowed chest movement.

The results of the current study are consistent with past research, indicating that respiratory recovery positions do not change lung volumes and have minimal effect on

contractility of respiratory accessory muscles. The results of this study were restricted to only healthy individuals. Therefore, to acquire data that is more applicable to COPD patients, future studies should include participants who have COPD or a pulmonary disorder. Also, the current study focused on accessory muscle recovery positions, but did not require that the participants perform any physical activity upon data collection. Further research should be performed to see if the respiratory accessory muscle activity increases in the desired positions secondary to exercise and is applicable to athletes, as to which positions help them recover more effectively. This study looked at the EMG of the muscles for 10 seconds of heavy breathing and only 1 major breath for lung volumes. Minute ventilation for lung volumes in the positions and EMG findings for potential fatigue could also provide insight into this topic with future research. It would also be beneficial to investigate the role of abdominal musculature in respiratory recovery. If future research is conclusive with Gosselink et al.'s findings, adding abdominal strengthening to COPD therapy interventions would be highly beneficial.

CHAPTER V

CONCLUSION

The evidence from this study shows that there is an increase in EMG activity for bilateral sternocleidomastoid and upper trapezius muscles in the hands on head position, producing significant differences compared to the control position of standing with arms resting to the side. There also was a significant difference in values for EMG activity in the latissimus dorsi muscle in the position of leaning forward with hands on the knees. Despite the increase in muscle activity in these positions, pulmonary function measured using spirometry did not produce any significant values in all measurements taken. These positions may provide relief and allow for better accessory respiratory muscle activation and use as a recovery position for COPD patients despite the results not producing significant recovery in healthy participants. The two positions with increased EMG activity should be demonstrated to clients with COPD as a recovery position option during situations of shortness of breath.

APPENDIX

May 28, 2015

Principal Investigator:	David Relling, P.T., Ph.D.
Project Title:	EMG Activity of Accessory Muscles of Breathing During Recovery Positions
IRB Project Number:	IRB-201505-361
Project Review Level:	Expedited 4
Date of IRB Approval:	05/28/2015
Expiration Date of This Approval:	05/27/2016
Consent Form Approval Date:	05/28/2015

The application form and all included documentation for the above-referenced project have been reviewed and approved via the procedures of the University of North Dakota Institutional Review Board.

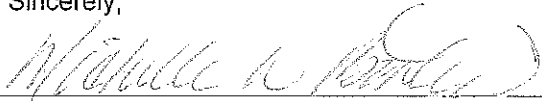
Attached is your original consent form that has been stamped with the UND IRB approval and expiration dates. Please maintain this original on file. **You must use this original, stamped consent form to make copies for participant enrollment. No other consent form should be used.** It must be signed by each participant prior to initiation of any research procedures. In addition, each participant must be given a copy of the consent form.

Prior to implementation, submit any changes to or departures from the protocol or consent form to the IRB for approval. No changes to approved research may take place without prior IRB approval.

You have approval for this project through the above-listed expiration date. When this research is completed, please submit a termination form to the IRB. If the research will last longer than one year, an annual review and progress report must be submitted to the IRB prior to the submission deadline to ensure adequate time for IRB review.

The forms to assist you in filing your project termination, annual review and progress report, adverse event/unanticipated problem, protocol change, etc. may be accessed on the IRB website:
<http://und.edu/research/resources/human-subjects/>

Sincerely,



Michelle L. Bowles, M.P.A., CIP
IRB Coordinator

MLB/jle

Enclosures

Cc: Chair, Physical Therapy

University of North Dakota Human Subjects Review Form
January 2015 Version

All research with human participants conducted by faculty, staff, and students associated with the University of North Dakota, must be reviewed and approved as prescribed by the University's policies and procedures governing the use of human subjects. It is the intent of the University of North Dakota (UND), through the Institutional Review Board (IRB) and Research Development and Compliance (RD&C), to assist investigators engaged in human subject research to conduct their research along ethical guidelines reflecting professional as well as community standards. The University has an obligation to ensure that all research involving human subjects meets regulations established by the United States Code of Federal Regulations (CFR). When completing the Human Subjects Review Form, use the "IRB Checklist" for additional guidance.

Please provide the information requested below. Handwritten forms are not accepted – responses must be typed on the form.

Principal Investigator: David Relling, PT, Ph.D.

Telephone: 777-4091

E-mail Address: david.relling@med.und.edu

Complete Mailing Address: Dept of PT Rm 1510, 501 N Columbia Rd Stop 9037, Grand Forks ND 58202-9037

School/College: Medicine and Health Sciences

Department: Physical Therapy

Student Advisor (if applicable): _____

Telephone: _____

E-mail Address: _____

Address or Box #: _____

School/College: _____

Department: _____

***** All IRB applications must include a Key Personnel Listing.**

Project Title: EMG activity of Accessory Muscles of Breathing during Recovery Positions

Proposed Project Dates: Beginning Date: May 26, 2015

Completion Date: May 1, 2016

(Including data analysis)

Funding agencies supporting this research: N/A

Did the contract with the funding entity go through UND Grants and Contracts Administration? YES or NO
Attach a copy of the contract. Do not include any budgetary information. The IRB will not be able to review the study without a copy of the contract with the funding agency.

Does any researcher associated with this project have an economic interest in the research, or act as an officer or a director of any outside entity whose financial interests would reasonably appear to be affected by the research? If yes, submit on a separate piece of paper an additional explanation of the financial interest. The Principal Investigator and any researcher associated with this project should have a Financial Interests Disclosure Document on file with their department.

YES or NO

Will any research participants be obtained from another organization outside the University of North Dakota (e.g., hospitals, schools, public agencies, American Indian tribes/reservations)?

YES or NO

Will any data be collected at or obtained from another organization outside the University of North Dakota?

YES or NO

If yes to either of the previous two questions, list all organizations:

Letters from each organization must accompany this proposal. Each letter must illustrate that the organization understands its involvement and agrees to participate in the study. Letters must include the name and title of the individual signing the letter and should be printed on organizational letterhead.

Does any external site where the research will be conducted have its own IRB? YES NO N/A

If yes, does the external site plan to rely on UND's IRB for approval of this study? YES NO N/A
(If yes, contact the UND IRB at 701 777-4279 for additional requirements)

If your project has been or will be submitted to other IRBs, list those Boards below, along with the status of each proposal.

_____ Date submitted: _____ Status: Approved Pending
_____ Date submitted: _____ Status: Approved Pending

(include the name and address of the IRB, contact person at the IRB, and a phone number for that person)

Type of Project: Check "Yes" or "No" for each of the following.

- YES or NO New Project YES or NO Dissertation/Thesis/Independent Study
 YES or NO Continuation/Renewal YES or NO Student Research Project
 YES or NO Is this a Protocol Change for previously approved project? If yes, submit a signed Protocol Change Form, along with a signed copy of this form with the changes bolded or highlighted.
 YES or NO Does your project involve abstracting medical record information? If yes, complete the HIPAA Compliance Application and submit it with this form.
 YES or NO Does your project include Genetic Research?

Subject Classification: This study will involve subjects who are in the following special populations: Check all that apply.

- Children (< 18 years) UND Students
 Prisoners Pregnant Women/Fetuses
 Cognitively impaired persons or persons unable to consent
 Other _____

Please use appropriate checklist when children, prisoners, pregnant women, or people who are unable to consent will be involved in the research.

This study will involve: Check all that apply.

- Deception (Attach Waiver or Alteration of Informed Consent Requirements) Stem Cells
 Radiation Discarded Tissue
 New Drugs (IND) IND # _____ Attach Approval Fetal Tissue
 Investigational Device Exemption (IDE) # _____ Attach Approval Human Blood or Fluids
 Non-approved Use of Drug(s) Other _____
 None of the above will be involved in this study

I. Project Overview

Please provide a brief explanation (limit to 200 words or less) of the rationale and purpose of the study, introduction of any sponsor(s) of the study, and justification for use of human subjects and/or special populations (e.g., vulnerable populations such as children, prisoners, pregnant women/fetuses).

During physical activity, individuals with pulmonary disease experience shortness of breath, fatigue, and limited function. Fear of shortness of breath spirals into sedentary behavior and declining physical function. Recovery positions, such as leaning forward while supporting forearms onto a table, have been proposed to augment breathing control and reduce shortness of breath. It has been postulated that increased activity of muscles on the trunk, called accessory muscles of breathing, is a key component of breath recovery. The purpose of this study is to assess accessory muscle activity using electromyography (EMG) and size of breath volume in different recovery positions.

II. Protocol Description

Please provide a thorough description of the procedures to be used by addressing the instructions under each of the following categories.

1. Subject Selection.

- a) Describe recruitment procedures (i.e., how subjects will be recruited, who will recruit them, where and when they will be recruited and for how long) and include copies of any advertisements, fliers, etc., that will be used to recruit subjects. Subjects will be recruited from the UND professional physical therapy classes. A flier (see attached) will be displayed in the department during the summer 2015 and fall 2015 semesters. The principle investigator will announce the posting of the flier to students enrolled in the professional program.
- b) Describe your subject selection procedures and criteria, paying special attention to the rationale for including subjects from any of the categories listed in the "Subject Classification" section above. Subjects must be apparently healthy, 18 years of age, free of pulmonary disease, and no recent injuries or conditions affecting the ability to breath or assume the experimental positions. The use of UND students in the professional physical therapy program reflects a sample of convenience.
- c) Describe your exclusionary criteria and provide a rationale for excluding subject categories. Under the age of 18 due to the inability to provide their own consent (minor). Subjects with pulmonary disease or recent injuries or conditions affecting the ability to breath or assume experimental positions are excluded because the study is expected to challenge the pulmonary system during assessment of the volume of breathing with a spirometer. Additionally, injuries or conditions affecting the ability to breath or assume the testing positions could produce undue discomfort for the subject. The EMG electrodes utilize a tape-like adhesive for adherence to the skin and therefore individuals with tape allergies will be excluded. Therefore, apparently healthy individuals over the age of 18 will be utilized for the study.
- d) Describe the estimated number of subjects that will participate and the rationale for using that number of subjects. It is estimated that 30 subjects will be recruited into the study. Each subject will serve as their own control in the different breathing recovery positions. The 30 subjects are expected to provide a normative distribution of EMG and pulmonary function testing for healthy individuals. At the same time, this number of subjects should provide the statistical power needed to identify significant differences in EMG activity or lung volumes due to the different recovery positions.
- e) Specify the potential for valid results. If you have used a power analysis to determine the number of subjects, describe your method.
A statistical power analysis was not performed. However, in previous studies with EMG we have observed 20-30 subjects provides adequate data to determine effectiveness of position or movement changes on the muscles being studied.

2. Description of Methodology.

- a) Describe the procedures used to obtain informed consent.
The principle investigator will announce the availability of the study to students in the professional program. A flyer will be used to provide additional information. Potential participants will be provided with an overview of the purpose, study design, risks and results/outcomes of the study. Each subject will be informed of the potential for adverse effects. Subjects will be provided with the written consent form. Time will be allowed for any potential questions or concerns. Prior to the initiation of subject participation, each subject must provide verbal and written consent (see consent form)
- b) Describe where the research will be conducted. Document the resources and facilities to be used to carry out the proposed research. Please note staffing, funding, and space available to conduct this research.
The research will be conducted in the Department of Physical Therapy in the School of Medicine & Health Sciences at the University of North Dakota. The department has both electromyography (EMG) software and hardware available for this project. The Noraxon Telemetry 2400 unit for EMG data collection and analysis is available within the department. In addition, the department has a SpiroPro (SensorMedics Corp, Yorba Linda CA) spirometer to obtain breathing volumes. The

principle investigator has experience in utilizing both pieces of equipment and software. The UND PT department will provide the EMG electrodes and spirometer mouthpieces as needed.

- c) Indicate who will carry out the research procedures.

The principle investigator, Dr. David Relling, will perform subject consent and oversee all aspects of the research project. Students in the professional physical therapy program (Joel Kramer, Kelsey Meyer, Eric Nefstead, and Daniel Vilaubi) will assist with subject recruitment, intervention (data collection) and data analysis. Dr. Relling has training and experience using both the EMG system and SpiroPro spirometer. Joel Kramer, Kelsey Meyer, Eric Nefstead, and Daniel Vilaubi have undergone training on the EMG system and will obtain proficiency with the SpiroPro spirometer prior to initiation of the study.

- d) Briefly describe the procedures and techniques to be used and the amount of time that is required by the subjects to complete them.

Subjects will initially be fit with pre-gelled, self-adhesive surface electrodes placed over the motor points of the relevant muscles. The electrodes collect underlying electrical activity within the subject's muscles but do not provide any electrical shock or current to the subject. The muscles to be monitored include upper trapezius, sternocleidomastoid, latissimus dorsi, pectoralis major, and serratus anterior (See attached diagram). The subjects will be asked to wear tank tops to facilitate access to the muscles and protect modesty. Prior to electrode placement, the skin will be prepared in a standardized fashion and skin impedance will be measured to ensure adequate electrical conduction at each site. Preparation of the skin includes removing excess hair from the electrode site with an electric clipper and wiping the skin surface lightly with 400 grit sandpaper followed by wiping the area with isopropyl alcohol wipes. The electrodes will be connected to a transmitter which will be placed in a belt around the subject's waist. The EMG signals will be transmitted to a receiver and then to a computer. Raw EMG data will be obtained for analysis. Breathing volumes will be assessed using the SpiroPro spirometer. Nose clips will be placed on the subjects nose to assure accurate breathing volume through the spirometer. Subjects will place the spirometer mouthpiece into the mouth and breath deeply for 15 seconds. The volume in 15 seconds will be used to calculate maximal minute volume. Each subject will perform one session of deep breathing at each of the body positions used for the study (relaxed standing, standing with hands clasped overhead, standing with hands on knees, and sitting with arms supported on a table). The EMG activity will be collected while the subject is performing the deep breathing to determine the activity in the accessory muscles of breathing. The four experimental body positions will be assigned randomly with 2 minutes of rest provided between each session of deep breathing.

- e) Describe audio/visual procedures and proper disposal of tapes.

No audio or visual data will be collected during the study.

- f) Describe the qualifications of the individuals conducting all procedures used in the study.

David Relling is a faculty member in the department of physical therapy. He has performed research projects with EMG and spirometers in the past. All key personnel have received training on the EMG equipment. All key personnel have completed IRB training.

- g) Describe compensation procedures (payment or class credit for the subjects, etc.).

No compensation will be provided for subjects participating in the study.

Attachments Necessary: Copies of all instruments (such as survey/interview questions, data collection forms completed by subjects, etc.) must be attached to this proposal.

3. Risk Identification.

- a) Clearly describe the anticipated risks to the subject/others including any physical, emotional, and financial risks that might result from this study.

The potential physical risks associated with this study are minimal. The EMG electrode placement and analysis is a non-invasive procedure utilized in clinical practice. Minor skin irritation from the skin preparation and EMG electrodes is possible. The use of a spirometer and assessing breathing

volumes with minute ventilation may lead to dryness and irritation of the mouth. Water will be available for subjects during the study.

- b) Indicate whether there will be a way to link subject responses and/or data sheets to consent forms, and if so, what the justification is for having that link.

Subject's names will not be used in any reports of the results of this study. Each participant will complete a written consent form. There will be no association between the written consent form and the subjects data. At the completion of the study, the research data and the consent forms will be stored in separate, locked locations in the Department of Physical Therapy for 3 years at which point the forms and data will be destroyed. Data will only be reported in aggregate form to protect the confidentiality of all subjects.

- c) Provide a description of the data monitoring plan for all research that involves greater than minimal risk.
N/A

- d) If the PI will be the lead-investigator for a multi-center study, or if the PI's organization will be the lead site in a multi-center study, include information about the management of information obtained in multi-site research that might be relevant to the protection of research participants, such as unanticipated problems involving risks to participants or others, interim results, or protocol modifications.

N/A

4. Subject Protection.

- a) Describe precautions you will take to minimize potential risks to the subjects (e.g., sterile conditions, informing subjects that some individuals may have strong emotional reactions to the procedures, debriefing, etc.).

Each subject will be provided with their own spirometer mouthpiece. New, clean disposable electrodes will be utilized for each subject. The possibility of skin irritation will be minimized by proper skin preparation and subject screening prior to participation. Subjects will be informed of the placement of electrodes to prevent emotional reactions to concerns about impeding on the subjects personal space. Investigators will use appropriate draping of the subject during preparation and placement of EMG electrodes. The investigator(s) or participant may stop the experiment at any time if the participant is experiencing discomfort, pain, fatigue, or any other symptoms that may be detrimental to their health. All subjects will be allowed to terminate their participation in this study at any time without prejudice.

- b) Describe procedures you will implement to protect confidentiality and privacy of participants (such as coding subject data, removing identifying information, reporting data in aggregate form, not violating a participants space, not intruding where one is not welcome or trusted, not observing or recording what people expect not to be public, etc.). If participants who are likely to be vulnerable to coercion and undue influence are to be included in the research, define provisions to protect the privacy and interests of these participants and additional safeguards implemented to protect the rights and welfare of these participants.

Subject data will not be linked to the consent form in order to protect the confidentiality of the subjects.

Data collection forms and electronic data collection EMG files will be linked together using an alpha-numeric code. Data will only be reported in aggregate form to assure privacy of the subjects.

Participants will wear appropriate clothing to allow access to the EMG electrode sites. However, researchers will utilize appropriate draping with sheets and towels during placement of the electrodes to assure patient comfort and modesty.

-
- c) Indicate that the subject will be provided with a copy of the consent form and how this will be done.
Prior to participation in this study, each subject will read and sign a consent form. Participants in this study will all be capable of independent decision making and will sign a consent form stating their understanding and willingness to participate in this study. Participants will be encouraged to ask any questions regarding the consent form to ensure their understanding of the document. Each participant will be provided the opportunity to receive a copy of the consent form for their records.
- d) Describe the protocol regarding record retention. Please indicate that research data from this study and consent forms will both be retained in separate locked locations for a minimum of three years following the completion of the study.

- Describe: 1) the storage location of the research data (separate from consent forms and subject personal data)
2) who will have access to the data
3) how the data will be destroyed
4) the storage location of consent forms and personal data (separate from research data)
5) how the consent forms will be destroyed

Participant consent forms and data (collection sheets and electronic files) will be stored separately and secured in separate locked locations in the Department of Physical Therapy. Only the principal investigator will have access to both the consent forms and data. Subject data AND CONSENT FORMS WILL BE RETAINED IN RM 1521 IN SEPARATE, LOCKED FILE CABINETS. After a period of 3 years from the completion of the study, the consent forms and data collection sheets will be shredded. Electronic data will be deleted or destroyed from all disks/drives.

- e) Describe procedures to deal with adverse reactions (referrals to helping agencies, procedures for dealing with trauma, etc.). The investigators or participant may stop the experiment at any time if the participant is experiencing discomfort, pain, abnormal fatigue, or any other symptoms that may be detrimental to their health. If subjects consent to participate they will be allowed to terminate their participation in this study at any time without prejudice or jeopardizing any future relationships with the UND Department of Physical Therapy. Medical treatment will be provided to each subject as needed, including first aid, CPR, and follow-up care as that provided to a member of the general public in a similar circumstance.
- f) Include an explanation of medical treatment available if injury or adverse reaction occurs and responsibility for costs involved.
In the event an adverse event occurs during participation in this study, the subject will be prompted to seek immediate medical attention. All incurred medical expenses will be the responsibility of the subject or the subject's third-party payer.

III. Benefits of the Study

Clearly describe the benefits to the subject and to society resulting from this study (such as learning experiences, services received, etc.). **Please note:** extra credit and/or payment are not benefits and should be listed in the Protocol Description section under Methodology.

Possible benefits of this study include but are not limited to: 1) furthering the knowledge concerning the muscle activity used in different breath recovery positions; 2) furthering the knowledge concerning the breath volume in different recovery positions; 3) further research may be stimulated. Subjects participating in the study will not receive any compensation nor will they incur any cost associated with this study.

IV. Consent Form

Clearly describe the consent process below and be sure to include the following information in your description (Note: Simply stating 'see attached consent form' is not sufficient. The items listed below must be addressed on this form.):

- 1) The person who will conduct the consent interview
- 2) The person who will provide consent or permission
- 3) Any waiting period between informing the prospective participant and obtaining consent
- 4) Steps taken to minimize the possibility of coercion or undue influence
- 5) The language to be used by those obtaining consent
- 6) The language understood by the prospective participant or the legally authorized representative
- 7) The information to be communicated to the prospective participant or the legally authorized representative

The person to conduct the consent interview will be Dr. David Relling. Consent will be provided by the subject. Since the study is a one time event with minimal risk, there will be no waiting time between informing the subject and consent. The investigator will announce the opportunity to participate and post the appropriate sign while key personnel recruit subjects. Removing the PI from recruitment should decrease undue influence from the faculty lead study. **ENGLISH WILL BE USED FOR OBTAINING CONSENT AND ALL SUBJECTS MUST BE ABLE TO UNDERSTAND AND UTILIZE ENGLISH.** Information communicated to the prospective participant will include a reading of the study purpose and what will happen from the informed consent form.

A copy of the consent form must be attached to this proposal. If no consent form is to be used, document the procedures to be used to protect human subjects, and complete the Application for Waiver or Alteration of Informed Consent Requirements. Refer

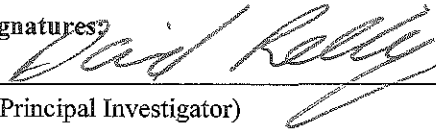
to form IC 701-A, Informed Consent Checklist, and make sure that all the required elements are included. **Please note:** All records attained must be retained for a period of time sufficient to meet federal, state, and local regulations; sponsor requirements; and organizational policies. The consent form must be written in language that can easily be read by the subject population and any use of jargon or technical language should be avoided. **The consent form should be written at no higher than an 8th grade reading level**, and it is recommended that it be written in the third person (please see the example on the RD&C website). A two inch by two inch blank space must be left on the bottom of each page of the consent form for the IRB approval stamp.

Necessary attachments:

- Signed Student Consent to Release of Educational Record Form (students and medical residents only);
- Investigator Letter of Assurance of Compliance; (all researchers)
- Consent form, or Waiver or Alteration of Informed Consent Requirements (Form IC 702-B)
- Key Personnel Listing
- Surveys, interview questions, etc. (if applicable);
- Printed web screens (if survey is over the Internet); and
- Advertisements (flyer, social media postings, email/letters, etc.).

By signing below, you are verifying that the information provided in the Human Subjects Review Form and attached information is accurate and that the project will be completed as indicated.

Signatures:


(Principal Investigator)

~~4/25/2015~~ 5/21/2015
Date:

(Student Advisor)

Date:

*****All students and medical residents must list a faculty member as a student advisor on the first page of the application and must have that person sign the application.*****

Requirements for submitting proposals:

Additional information can be found on the IRB website at: <http://und.edu/research/resources/human-subjects/index.cfm>

Original, signed proposals and all attachments, along with the necessary number of copies (see below), should be submitted to: Institutional Review Board, 264 Centennial Drive Stop 7134, Grand Forks, ND 58202-7134, or brought to Room 106, Twamley Hall.

Required Number of Copies:

- Expedited Review: Submit the signed original and 1 copy of the entire proposal.
- Full Board Review: Submit the signed original and 22 copies of the entire proposal by the deadline listed on the IRB website: <http://und.edu/research/resources/human-subjects/meeting-schedule.cfm>
- Clinical Medical Subcommittee and Full Board Review: Submit the signed original and 24 copies of the entire proposal by the deadline listed on the IRB website: <http://und.edu/research/resources/human-subjects/meeting-schedule.cfm>

Prior to receiving IRB approval, researchers must complete the required IRB human subjects' education. Please go to: <http://und.edu/research/resources/human-subjects/human-subject-education.cfm>

The criteria for determining what category your proposal will be reviewed under is listed on page 3 of the IRB Checklist. Your reviewer will assign a review category to your proposal. Should your protocol require full Board review, you will need to provide additional copies. Further information can be found on the IRB website regarding required copies and IRB review categories, or you may call the IRB office at 701 777-4279.

In cases where the proposed work is part of a proposal to a potential funding source, one copy of the completed proposal funding agency (agreement/contract if there is no proposal) must be attached to the completed Human Subjects Review proposal is non-clinical; 5 copies if the proposal is clinical-medical. If the proposed work is being conducted for pharmaceutical company, 5 copies of the company's protocol must be provided.

**INVESTIGATOR LETTER OF ASSURANCE OF COMPLIANCE
WITH ALL APPLICABLE FEDERAL REGULATIONS FOR THE
PROTECTION OF THE RIGHTS OF HUMAN SUBJECTS**

I David P. Relling, PT, Ph.D.
(Name of Investigator)

agree that, in conducting research under the approval of the University of North Dakota Institutional Review Board, I will fully comply and assume responsibility for the enforcement of compliance with all applicable federal regulations and University policies for the protection of the rights of human subjects engaged in research. Specific regulations include the Federal Common Rule for Protection of the Rights of Human Subjects 45 CFR 46. I will also assure compliance to the ethical principles set forth in the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research document, The Belmont Report.

I understand the University's policies concerning research involving human subjects and agree to the following:

1. Should I wish to make changes in the approved protocol for this project, I will submit them for review PRIOR to initiating the changes. (A proposal may be changed without prior IRB approval where necessary to eliminate apparent immediate hazards to the subjects or others. However, the IRB must be notified in writing within 72 hours of any change, and IRB review is required at the next regularly scheduled meeting of the full IRB.)
2. If any problems involving human subjects occur, I will immediately notify the Chair of the IRB, or the IRB Coordinator.
3. I will cooperate with the UND IRB by submitting Research Project Review and Progress Reports in a timely manner.

I understand the failure to do so may result in the suspension or termination of proposed research and possible reporting to federal agencies.


Investigator Signature

5/21/15
Date

**UNIVERSITY OF NORTH DAKOTA
INSTITUTIONAL REVIEW BOARD
KEY PERSONNEL LISTING**

	Names of Research Personnel		Position (select from drop-down menu)	Highest Academic Degree (High School, B.S, M.A., Ph.D., M.D., etc.)	Licenses/Certifications (if applicable)	Responsibilities (check all that apply)				
	First Name	Last Name				Consent Subjects	Recruit Subjects	Research Design	Intervention	Data Analysis
1	David	Relling	Faculty	Ph.D.	PT	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2	Joel	Kramer	Graduate student			<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
3	Kelsey	Meyer	Graduate student			<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
4	Eric	Nefstead	Graduate student			<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
5	Daniel	Vilaubi	Graduate student			<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
6						<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7						<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8						<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9						<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10						<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

* *Attach proof of education in human subjects research for all non-UND personnel*

ID #: PulmEMG15-

**TITLE: EMG Activity of Accessory Muscles of
Breathing during Recovery Positions**

Subject Questionnaire and Data Collection

Age: _____

Height _____

Gender: _____

Weight _____

- 1) Do you have any difficulty with breathing or physical activity? YES/NO
If YES, please explain: _____
- 2) Have you had any injuries to your chest or back in the past 3 months? YES/NO
If YES, please explain: _____
- 3) Have you experienced itching, rash or irritation from bandages or adhesives on
tape? YES/NO
If YES, please explain: _____

POSITION	MINUTE VENTILATION	
Standing Arms at Sides		
Standing Hands on Head		
Standing Hands on Knees		
Sitting Arms Supported		

EXPECTED LUNG VOLUMES (from prediction equations based on age, gender & height) :

MEASURE	PREDICTION	ACTUAL
FVC		
FEV ₁		
IRV		
ERV		

INFORMED CONSENT

TITLE: EMG Activity of Accessory Muscles of Breathing during Recovery Positions

PROJECT DIRECTOR: David Relling, PT, Ph.D.

PHONE # (701)777-4091

DEPARTMENT: Physical Therapy

STATEMENT OF RESEARCH

A person who is to participate in the research must give his or her informed consent to such participation. This consent must be based on an understanding of the nature and risks of the research. This document provides information that is important for this understanding. Research projects include only subjects who choose to take part. Please take your time in making your decision as to whether to participate. If you have questions at any time, please ask.

WHAT IS THE PURPOSE OF THIS STUDY?

You are invited to take part in a research study conducted by David Relling, a faculty member of the Department of Physical Therapy at the University of North Dakota. The purpose of this study is to better understand the effect of recovery body positions on breathing volume and activity of accessory muscles of breathing. Example recovery positions include hands on your knees or hands on your head. Accessory muscles of breathing include larger muscles of the chest, neck and back. You were selected because you are over the age of 18, do not have any lung diseases, difficulty breathing or recent injuries.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 30 people will take part in this study at the University of North Dakota.

HOW LONG WILL I BE IN THIS STUDY?

Your participation in the study will last for 1 session of approximately 1 hour. You will need to visit the physical therapy department (501 N Columbia Rd, Room 1510, and its research lab, Room 2541) where the study will take place.

WHAT WILL HAPPEN DURING THIS STUDY?

You will complete a form that asks about your age, height, weight, gender, breathing problems or injuries. The information is needed to predict the "normal" or expected air capacity of your lungs and eligibility to participate in the study. Following completion of the form, the researchers will prepare to collect information regarding your muscles' activity using electromyography (EMG). EMG uses small, adhesive-backed electrodes attached to the skin and a device that can detect the electrical activity present in muscles at rest and in action. The device does not give off an electrical current or shock to your body—it only detects electrical activity present in muscles over which electrodes are attached. The researchers will clip any hair present over areas of muscle on which electrodes are to be placed. This will be followed by rubbing the skin lightly with sandpaper and an alcohol wipe in order to improve the ability to detect electrical activity. The electrodes will convey electrical information to the device for actual measurement. Once electrodes are in place, computer information will be recorded as you breath strongly through a mouthpiece connected to a spirometer for fifteen seconds. The spirometer measures the amount of air you inhale and exhale. You will perform the spirometer activity in four different recovery positions: standing with arms relaxed, standing with hands on your head, standing with hands on your knees and sitting with forearms on a table.

WHAT ARE THE RISKS OF THE STUDY?

There may be some risk from being in this study, such as the small risk of mild skin irritation at the site of the electrode that reads the muscle activity, a common short-lasting occurrence in studies using EMG. Steps will be taken to ensure your modesty and comfort by covering areas where electrode application may approach more personal body areas, such as the chest, back and neck.

If you are pregnant or become pregnant during the study, we foresee no additional risks to you or the baby during the course of the research.

WHAT ARE THE BENEFITS OF THIS STUDY?

You may not benefit personally from being in this study. However, we hope that, in the future, other people might benefit from this study because results from this research may help the understanding of optimal positions and accessory muscles for overcoming difficulty with breathing.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY? WILL I BE PAID?

You will not have any costs for being in this research study other than perhaps traveling or parking costs. You will not be paid for being in this research study.

WHO IS FUNDING THE STUDY?

The University of North Dakota and the research team are receiving no payments from other agencies, organizations, or companies to conduct this research study.

CONFIDENTIALITY

The records of this study will be kept private to the extent permitted by law. In any report about this study that might be published, you will not be identified. Your study record may be reviewed by Government agencies, the UND Research Development and Compliance office, and the University of North Dakota Institutional Review Board.

Any information that is obtained in this study and that can be identified with you will remain confidential and will be disclosed only with your permission or as required by law. Confidentiality will be maintained by means of coding data and computer files with an independent number for each subject. You should know, however, that there are some circumstances in which we may have to show your information to other people. For example the law may require us to show your information to a court or to tell authorities if we believe you have abused a child, or you pose a danger to yourself or someone else. Confidentiality will be maintained by means of storing of all records and research information in separate locked file cabinets in Room 1521 of the Physical Therapy Department. All collected research information and records will be destroyed by shredding after 3 years.

If we write a report or article about this study, we will describe the study results in a summarized manner so that you cannot be identified.

COMPENSATION FOR INJURY

In the event that this research activity results in an injury, treatment will be available including first aid, emergency treatment and follow-up care as needed. Payment for any such treatment is to be provided by you (you will be billed) or your third-party payer, if any (such as health insurance, Medicare, etc.) No funds have been set aside to compensate you in the event of injury. Also, the study staff cannot be responsible if you knowingly and willingly disregard the directions they give you.

IS THIS STUDY VOLUNTARY?

Your participation is voluntary. You may choose not to participate or you may discontinue your participation at any time without penalty or loss of benefits to which you are otherwise entitled. Your decision whether or not to participate will not affect your current or future relations with the University of North Dakota.

CONTACTS AND QUESTIONS

The researcher conducting this study is David Relling. You may ask any questions you have now or anytime during your participation in the study. If you later have questions, concerns, or complaints about the research please contact David Relling in the Physical Therapy Department at 777-2831 during the day and at (701)741-3481 after hours. If you have questions regarding your rights as a research subject, or if you have any concerns or complaints about the research, you may contact the University of North Dakota Institutional Review Board at (701) 777-4279.

- You may also call this number about any problems, complaints, or concerns you have about this research study.
- You may also call this number if you cannot reach research staff, or you wish to talk with someone who is independent of the research team.
- General information about being a research subject can be found by clicking "Information for Research Participants" on the web site:
<http://und.edu/research/resources/human-subjects/research-participants.cfm>

Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a copy of this form.

Subjects Name: _____

Signature of Subject

Date

I have discussed the above points with the subject or, where appropriate, with the subject's legally authorized representative.

Signature of Person Who Obtained Consent

Date

Date _____
Subject Initials: _____

This document identifies the EMG electrode placements for the study titled EMG Activity of Accessory Muscles of Breathing during Recovery Positions.

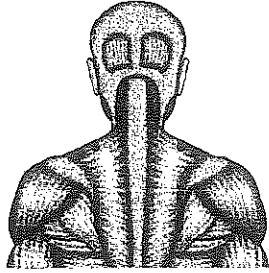


Figure 17-19A. Electrode placement for the upper trapezius site.
Source: Copyright © Clinical Resources, Inc.

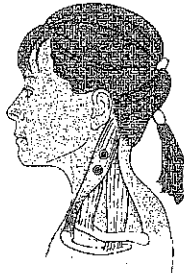


Figure 17-15A. Electrode placement for the SCM site.
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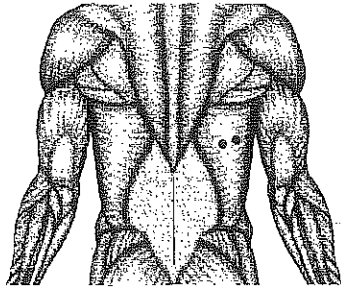


Figure 17-49A. Electrode placement for the latissimus dorsi site.
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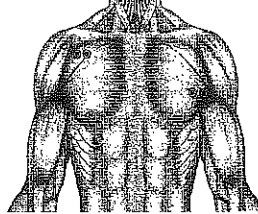


Figure 17-28A. Electrode placement for the pectoralis major clavicular (right side) and sternal (left side) sites.
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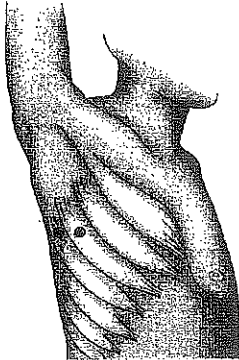


Figure 17-22A. Electrode placement for the serratus anterior site.
Source: Copyright © Clinical Resources, Inc.

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